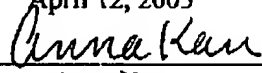


Patent Docket P1467R2

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of  Camellia W. Adams et al.  Serial No.: 09/602,812  Filed: June 23, 2000  For: Humanized Anti-ErbB2 Antibodies and Treatment with Anti-ErbB2 Antibodies	Group Art Unit: 1642  Examiner: Anne Holleran  Confirmation No: 9612  CUSTOMER NO: 09157  <small>Certificate of Facsimile Transmission Under 37 CFR § 1.8</small> <small>In accordance with CFR § 1.6(d), this correspondence addressed to Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450 is being transmitted to facsimile No. (703) 872- 9306</small>  April 12, 2005  Anna Kan
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**APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(b)**

Mail Stop Issue Fee  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Applicant requests reconsideration of the Director's determination of patent term adjustment (PTA) as communicated in the Notice of Allowance mailed on 12 January 2005. In particular, applicant requests the correction of a clerical error in the PALM record and the restoration of 236 days of PTA erroneously charged against applicant under 37 C.F.R. § 1.704(b).

This application is filed concurrently with a petition to accept the application after payment of the Issue Fee. The Director is authorized to charge applicant's Deposit Account No. 07-0630 for the fee required as specified in § 1.18(e) (\$200.00).

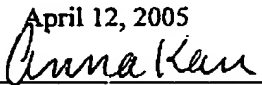
**Facts**

1. Attached is a printout of the Office's determination of PTA for this application, as provided on PAIR. The net PTA shown on the printout is 0 days, calculated as +203 days of PTO delay, -492 days of applicant delay, and no three-year delay.
2. (§ 1.705)(2)(i) For the following reasons, the correct PTA to which this application is entitled is 329 days plus the number of days from the date of the Notice of Allowance (12 January 2005) until the date that a patent is granted.

COPY

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Serial No.: 09/602,812

3. (§ 1.705)(2)(ii). The examination delays under §§ 1.702(a) and 1.703 that are correctly shown on the attached PAIR printout are the following:

- **40 days** for failing to mail a communication within 14 months of filing, for the interval between 23 August 2001 and 2 October 2001.
- **4 days** for failing to mail a communication within 4 months of the reply to the Office action filed on 2 June 2004, for the interval between 2 October 2004 and 6 October 2004.

The following examination delay under §§ 1.702(a) and 1.703 is not correctly calculated:

- **159 days** for failing to mail a communication within 4 months of a reply to an Office action, for the interval ending on 2 January 2004. The calculation is based on the filing of a reply on 27 March 2003. However, as shown on the papers filed in March 2003, the reply was in fact filed on 24 March 2003. Thus the actual examination delay corresponds to the interval between 24 July 2003 and 2 January 2004, a period of 162 days.

The indication that there is no "three-year" delay under §§ 1.702(b) and 1.703 is not correct. Such delay for this application is properly calculated as follows:

- The date that such delay began to accrue is 23 June 2003 (i.e., the third anniversary of the filing date.) Between that date and the mailing date of the Notice of Allowance, 12 January 2005, 573 days elapsed. The portion of this interval that overlaps the examination delay under § 1.702(a) calculated above is 197 days (193 days from 23 June 2003 to 2 January 2004, plus 4 days from 2 October 2004 to 6 October 2004). Accordingly, the net delay under §§ 1.702(b) and 1.703, as of the mailing date of the Notice of Allowance, is 376 days.

The sum of these delays is **582 days** (§ 1.703(f)).

4. (§ 1.705)(2)(iii) This application is not subject to a terminal disclaimer.

5. (§ 1.705)(2)(iv)(A) The reductions under § 1.704 as shown on the attached PAIR printout which applicant believes to be correct are the following:

- **31 days** for failing to file a reply within 3 months to the Office communication mailed on 1 April 2002, for the interval between 1 July 2002 and 1 August 2002.
- **61 days** for failing to file a reply within 3 months to the Office communication mailed on 31 December 2003, for the interval between 31 March 2004 and 2 June 2004.
- **85 days** for filing a supplemental paper (an IDS) after a reply to an outstanding action, for the interval between 2 June 2004 and 26 August 2004.

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- 15 days for filing a supplemental paper (an IDS) after a reply to an outstanding action, for the interval between 21 October 2004 and 5 November 2004.

An error in the recorded submission date of a reply to an Office action causes the following calculation to be incorrect:

- 64 days for failing to file a reply within 3 months to the Office communication, for the interval ending on 27 March 2003. The calculation is based on the filing of a reply on 27 March. However, as shown on the papers filed in March 2003, the reply was in fact filed on 24 March 2003. Thus the correct period in which applicant failed to engage in reasonable efforts to conclude prosecution is from 22 January 2003 to 24 March 2003, an interval of 62 days.

6. The PAIR entry for an Information Disclosure Statement (IDS) on 18 November 2003 does not correspond to a failure by the applicant to engage in reasonable efforts to conclude prosecution.

(a) On 28 April 2003, applicant filed an IDS in compliance with 37 C.F.R. §§ 1.97 and 1.98. Attached are a postcard returned to the applicant and stamped by the Office indicating that the Office did receive an IDS on that date and a copy of the form PTO-1449 as filed by applicant on that date. This submission is also reflected in the PAIR entry dated 28 April 2003.

(b) No papers were in fact filed on 18 November 2003. The PALM entry on that date appears to correspond to the 28 April 2003 IDS. The papers in the PTO Image File Wrapper for the 18 November 2003 entry bear a PTO mailroom date stamp of 18 April 2003. The next Office action after 18 November, mailed on 2 January 2004, includes a copy of that PTO-1449 signed by the examiner on 19 November (copy attached), but no form PTO-1449 indicating that it was received by the Office on 18 November. Moreover, applicant has no record of any IDS or other paper actually filed on 18 November 2003. Accordingly, the entry of 236 days charged against applicant for the submission on 18 November 2003 is incorrect.

7. The total of the reductions under § 1.704, correctly calculated as set forth above, is 253 days.

8. The record indicates that on 9 May 2003, applicant filed a paper conveying copies of slides presented at a personal interview held on 28 April 2003. As the transmittal paper indicates, the submission provided only information that had already been presented to the examiner.

#### Discussion

Two corrections to the calculation of patent term adjustment flow from the incorrect entry in the PALM record of the reply filed in fact on 24 May 2003. As the recorded date of 27 May 2003 is plainly a clerical error, applicant requests correction.

Serial No.: 09/602,812

This application is eligible for the "three year guarantee" provisions of 35 U.S.C. § 154(b) implemented at 37 C.F.R. § 1.704(b). The application is not subject to any of the exclusions of time from the period of delay enumerated in the statute. Accordingly, applicant requests a full adjustment for the delay in granting a patent that corresponds to the time greater than three years that the application is pending before the Office, less the time that overlaps other periods of examination delay, as calculated above.

The PALM entry for an Information Disclosure Statement on 18 November 2003 reflects an error by the Office in docketing papers that were in fact filed on 28 April 2003. Because this filing does not correspond to a failure to engage in reasonable efforts to conclude prosecution, no reduction of PTA under § 1.704 properly results. Applicant requests correction of the erroneous calculation due to this clerical error.

Finally, applicant calls to the Office's attention that the paper filed on 9 May 2003 does not appear in the PALM record, and it has not factored into the calculation of PTA. Applicant believes that this result is correct. Although the paper was filed after the filing of a reply to an outstanding Office action, it provided only copies of materials that had been presented to the examiner at the personal interview of 28 April 2003. Thus, it was effectively an extension of the interview. Because the paper did not present argument or evidence which required further consideration or treatment by the examiner, applicant believes that it does not constitute a failure to engage in reasonable efforts to conclude prosecution and is properly omitted from the determination of reductions to term adjustment.

#### Conclusion

Applicant respectfully requests correction of the Office's records and revision of the Office's calculation of term adjustment as set forth above.

Respectfully submitted,  
GENENTECH, INC.

Date: April 12, 2005

By: 

Wendy Lee

Reg. No. 40,378

Telephone No. (650) 225-1994

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## Patent Term Adjustment (PTA) for application number: 09/602,812

	Days
Filing or 371(c) Date: 06-23-2000	USPTO Delay (PTO): 203
Issue Date of Patent:	Three Years:
Pre-Issue Petitions (days): +0	Applicant Delay (APPL): 492
Post-Issue Petitions (days): +0	Total PTA: 0
USPTO Adjustment (days): +0	Explanation of Calculations

Select Search Option

Continuity Data

Search

File History

Image File Wrapper

## Patent Term Adjustment History

Date	Contents Description	PTO (days)	APPL (days)
01-12-2005	Mail Notice of Allowance		
01-12-2005	Mail Examiner's Amendment		
01-10-2005	Issue Revision Completed		
01-10-2005	Examiner's Amendment Communication		
01-10-2005	Notice of Allowance Data Verification Completed		
01-10-2005	Notice of Allowability		
11-05-2004	Reference capture on IDS		
11-05-2004	Information Disclosure Statement (IDS) Filed		15
11-02-2004	Date Forwarded to Examiner		↑
10-21-2004	Response after Non-Final Action		↑
10-21-2004	Workflow incoming amendment IFW		
10-06-2004	Mail Non-Final Rejection	4	
10-01-2004	Non-Final Rejection	↑	
08-26-2004	Information Disclosure Statement (IDS) Filed	↑	85
08-02-2004	Mail Examiner Interview Summary (PTOL - 413)	↑	↑
07-29-2004	Examiner Interview Summary Record (PTOL - 413)	↑	↑
07-27-2004	Reference capture on IDS	↑	↑
07-22-2002	Reference capture on IDS	↑	↑
07-17-2002	Reference capture on IDS	↑	↑
11-18-2003	Reference capture on IDS	↑	↑
11-18-2003	Information Disclosure Statement (IDS) Filed	↑	236
07-26-2002	Information Disclosure Statement (IDS) Filed	↑	↑
07-22-2002	Information Disclosure Statement (IDS) Filed	↑	↑
07-17-2002	Information Disclosure Statement (IDS) Filed	↑	↑
04-12-2001	Information Disclosure Statement (IDS) Filed	↑	↑
01-29-2001	Information Disclosure Statement (IDS) Filed	↑	↑
09-01-2000	Reference capture on IDS	↑	↑

05-10-2004	Date Forwarded to Examiner	↑	↑
06-02-2004	Response after Non-Final Action	↑	61
06-02-2004	Request for Extension of Time - Granted		↑
06-02-2004	Workflow incoming amendment IEW		↑
01-27-2004	Information Disclosure Statement (IDS) Filed		↑
01-02-2004	Mail Non-Final Rejection	159	↑
12-31-2003	Non-Final Rejection	↑	
05-06-2003	Date Forwarded to Examiner	↑	
05-06-2003	Supplemental Response	↑	
04-28-2003	Information Disclosure Statement (IDS) Filed	↑	
04-28-2003	Examiner Interview Summary Record (PTOL-413)	↑	
03-27-2003	Date Forwarded to Examiner	↑	
03-27-2003	Response after Non-Final Action	↑	64
03-27-2003	Request for Extension of Time - Granted		↑
02-27-2003	Information Disclosure Statement (IDS) Filed		↑
10-22-2002	Mail Non-Final Rejection		↑
10-21-2002	Non-Final Rejection		
08-01-2002	Affidavit(s) (Rule 181 or 132) or Exhibit(s) Received		
08-16-2002	Date Forwarded to Examiner		
08-01-2002	Response after Non-Final Action		31
08-01-2002	Request for Extension of Time - Granted		↑
07-08-2002	Case Docketed to Examiner in GAU		↑
04-01-2002	Mail Non-Final Rejection		↑
02-25-2002	Non-Final Rejection		
12-12-2001	Information Disclosure Statement (IDS) Filed		↑
12-18-2001	Date Forwarded to Examiner		↑
12-12-2001	Response to Election / Restriction Filed		↑
10-02-2001	Mail Restriction Requirement	40	
10-01-2001	Requirement for Restriction / Election	↑	
10-31-2000	CRF Is Good Technically / Entered into Database	↑	
10-11-2000	Preliminary Amendment	↑	
10-10-2000	Case Docketed to Examiner in GAU	↑	
09-28-2000	Application Dispatched from OIPE	↑	
09-26-2000	Correspondence Address Change	↑	
07-24-2000	CRF Is Flawed Technically / Not Entered into Database	↑	
07-17-2000	IEW Scan & PACR Auto Security Review	↑	
06-23-2000	CRF Is Good Technically / Entered into Database	↑	
06-23-2000	Initial Exam Team m	↑	

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In re Application of: Camellia W. Adams et al.  
Serial No.: 09/602,812  
Filed On: June 23, 2000  
Hand Delivered On: April 28, 2003

Docket No.: P1467R2  
By: Wendy Lee  
Reg. No.: 40,378

The following has been received in the U.S. Patent Office on the date stamped:

<u>X</u>	Supplemental Information Disclosure Statement (dup)
<u>X</u>	Form 1449 with 69 References
<u>X</u>	Fees: \$ 180.00
<u>X</u>	Certificate of Hand Delivery

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